

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA)	Criminal No. 1:18-cr-10461-JGD
)	
v.)	
)	
EV3, INC.)	
)	
Defendant.)	
)	
)	

**EV3, INC.’S MOTION TO WAIVE THE PRESENTENCE REPORT AND
CONSOLIDATE THE PLEA AND SENTENCING HEARINGS**

Defendant ev3, Inc. hereby moves to waive the Presentence Report and consolidate the sentencing with the Rule 11 hearing scheduled for January 25, 2019 before this Court. This government investigation commenced in 2011 and, over the last several years, ev3 has engaged in extensive negotiations with the Department of Justice and the United States Attorney’s Office for the District of Massachusetts to resolve this matter. The ensuing Plea Agreement, filed with the Court on December 7, 2018, resolves the government’s investigation into ev3’s sales and marketing practices to physicians, between 2005 and 2009, concerning the Onyx Liquid Embolic System for use in certain procedures that were not approved by the FDA—colloquially known as “off label” promotion.

Federal Rule of Criminal Procedure 32(c)(1)(A)(ii) permits the Court to impose a sentence without the preparation of a Presentence Report if the Court finds that the information in the record is sufficient to enable it to exercise its sentencing authority meaningfully under 18 U.S.C. § 3553. ev3’s Sentencing Memorandum, along with the Information, the Plea Agreement, and other materials submitted to the Court, provides a detailed overview of the facts and circumstances that

gave rise to this resolution and allows the Court to exercise its sentencing authority under 18 U.S.C. § 3553. *See* Information, ECF No. 8 (Ex. A); Plea Agreement, ECF No. 8. The record also includes a Side Letter between the parties setting forth a comprehensive monitoring framework that will ensure that the sales and marketing of ev3 products remains compliant with the law in the future. *See* Side Letter, ECF No. 8 (Ex. B). These two agreements were the result of years of investigation, including more than two dozen substantive meetings with DOJ and extensive discussions with DOJ concerning the robust compliance program that now governs Onyx under ev3's successor company. A Presentence Report thus would not materially add to the information available to the Court to exercise its sentencing authority. Because the requirements of Rule 32(c)(1)(A)(ii) are met, ev3 respectfully requests that the Court waive the Presentence Report and investigation.

In the Plea Agreement, ev3 agrees to waive indictment and plead guilty pursuant to Federal Rule of Criminal Procedure 11(c)(1)(C) to the charges contained in the Information filed in this case. *See* Plea Agreement ¶ 1. As specified in the Plea Agreement executed by ev3 and DOJ, the agreed-upon disposition is as follows:

- Criminal fine in the amount of \$11,900,000;
- Forfeiture in the amount of \$6,000,000; and
- Special Assessment of \$125.

Plea Agreement ¶ 5. The Government is not seeking a term of probation in this matter in light of the fact that Medtronic “(1) acquired ev3 several years after the criminal conduct that resulted in th[e] [P]lea [A]greement, and had no prior knowledge of or involvement in such conduct; (2) took significant steps to prevent any future conduct of the kind that resulted in this Plea Agreement; (3) committed to certain compliance provisions related to the medical devices at

issue in this case; and (4) agreed to make the results of certain compliance assessments available to the United States" pursuant to the Side Letter. Plea Agreement ¶ 5(e).

As discussed herein, the Plea Agreement and Side Letter represent the conclusion of a comprehensive investigation by DOJ and negotiation between the parties that spanned over twenty meetings and many years. The Plea Agreement also provides that:

Defendant may seek sentencing by the District Court immediately following the Rule 11 plea hearing. The United States does not object to the Court proceeding to sentence Defendant immediately following the Rule 11 plea hearing or in the absence of a Presentence Report in this case. Defendant understands that the decision whether to proceed immediately with the sentencing proceeding following the plea hearing, and to do so without a Presentence Report, is exclusively that of the United States District Court.

Plea Agreement ¶ 3.

Because there is no need for a Presentence Report, and because there are no contested issues for the Court to resolve at sentencing, ev3 respectfully requests that the Court proceed to the sentencing phase of this matter at the Rule 11 hearing.

Finally, ev3 requests the Court's permission to allow Joshua S. Levy to tender the guilty plea on behalf of ev3. Federal Rule of Criminal Procedure 43(b)(1) provides that an "Organizational Defendant" "need not be present" if the "organization [is] represented by counsel who is present." Undersigned counsel has represented ev3 since the inception of this matter in May 2011. The Board of Directors of ev3 has been fully briefed on this matter and has authorized Mr. Levy to execute the Plea Agreement on behalf of the Company and to appear on behalf of the company at all court proceedings to effectuate the plea. Lastly, Medtronic's Senior Counsel for Global Investigations will be present for the hearing scheduled for January 25, 2019. Medtronic purchased Covidien in 2015, long after the conduct at issue and several years into the DOJ investigation.

The Government has advised undersigned counsel that it does not oppose ev3's motion to consolidate the sentencing with the Rule 11 hearing, and also does not oppose ev3's request to allow Mr. Levy to tender the guilty plea on behalf of ev3. The Government takes no position on ev3's motion to waive the Presentence Report.

WHEREFORE, ev3 respectfully requests that the Court waive the Presentence Report, conduct a consolidated plea and sentencing hearing in this matter, and allow Joshua S. Levy to take the plea on behalf of ev3.

Dated: January 18, 2019

Respectfully submitted,

Boston, Massachusetts

/s/ Joshua S. Levy

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Attorneys for Defendant,
ev3, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on January 18, 2019 a true and correct copy of the foregoing document was served electronically through the ECF system on all registered counsel of record as identified on the Notice of Electronic Filing (NEF).

/s/ Joshua S. Levy
Joshua S. Levy